In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1430V
Filed: May 5, 2017
Not to be Published

JUDITH WIERSEMA,	*	
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Petitioner,	*	
	*	
v.	*	Influenza vaccine; peripheral neuropathy; allergic reaction to Avelox; HIV; no evidence for demyelinating polyneuropathy; no expert report; dismissal on motion
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Nancy R. Meyers, Greensboro, NC, for petitioner.
Glenn A. MacLeod, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On October 28, 2016, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that, within a month of receiving influenza ("flu") vaccine on November 4, 2013, she had peripheral neuropathy. Pet. Preamble and at ¶¶ 6, 9, and 17.

Around Thanksgiving 2013, petitioner's primary care physician prescribed Avelox[2] for a

[1] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's enclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

[2] Avelox is a "trademark for a preparation of moxifloxacin hydrochloride." Dorland's Illustrated Medical Dictionary 184 (32nd ed. 2012) (hereinafter, "Dorland's"). Moxifloxacin hydrochloride is used "in the treatment of bacterial exacerbation of chronic bronchitis, acute sinusitis, community-acquired pneumonia,

supposed bladder infection and sore throat. Med. recs. Ex. 4, at 2. Petitioner reacted adversely to Avelox with facial swelling and was put on steroids which caused a moon face, buffalo hump suggestive of steroid effect, facial and neck swelling, and hoarseness. Id. Side effects to Avelox include swelling of the face, lips, tongue or throat, serious effects on the nerves, diarrhea, sore throat, and possible permanent nerve damage, muscle pain or weakness, and ill feeling.[3]

On March 3, 2017, during the third telephonic status conference the undersigned held in this case, petitioner's counsel stated that the undersigned's suggestion that petitioner had a reaction to Avalox was valid. Petitioner's counsel also stated she could not obtain an expert in support of petitioner's allegations. Petitioner moved to dismiss.

The undersigned **GRANTS** petitioner's motion and **DISMISSES** this case for failure to make a prima facie case of causation in fact.

FACTS

Prevaccination Medical Records

Petitioner was born on November 7, 1939, making her 77 years old.

On July 9, 2012, petitioner saw Dr. Robert Elgar. Med. recs. Ex. 3, at 662. She had a history of non-insulin-dependent diabetes mellitus, human immunodeficiency virus ("HIV") since 1989, colorectal cancer for which she had surgery in 1996, polyarthritis, neurogenic bowel and bladder, L4-L5 spinal stenosis, anemia, depression, gastroesophageal reflux disease ("GERD"), carpal tunnel syndrome, hiatal hernia, osteoporosis, left hip revision in 2011, right hip replacement, left hip replacement, right knee arthroscopy, Morton's neuroma in her left foot, bilateral cataract surgery, syncope, hyperlipidemia, and thoracic aneurysm. Id. at 662-63.

In November 2012, petitioner had her right fractured ankle repaired. Id. at 706.

On November 4, 2013, petitioner received flu vaccine. Med. recs. Ex. 1, at 3.

Postvaccination Medical Records

On November 26, 2013, petitioner saw Dr. Michael G. Gartlan, an ENT specialist, complaining of hoarseness and other difficulty breathing, and facial swelling of one month's duration. Med. recs. Ex. 4, at 2. Since Thanksgiving, she had been on the antibiotic Cefdinir for a supposed bladder infection and sore throat, which petitioner said did not help at all. Her doctor switched petitioner to Avelox and, two days afterward, her face swelled. She was put on Prednisone, and the swelling and hoarseness persisted. She had a history of chronic sinusitis, sudden hearing loss, smell and taste disorder, nose bleed (epistaxia), chronic serous otitis media, hoarseness, and environmental allergies. Id. Dr. Gartlan listed petitioner's allergies as Avelox,

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and skin and skin structure infections due to susceptible organisms." Id. at 1184.

[3] Avelox, Drugs.com, https://www.drugs.com/avelox.html (last visited May 5, 2017).

sulfonamides, penicillin, sulfa drugs, and fluoroquinolones. Id. at 3. On physical examination, petitioner had a moon face and buffalo hump suggestive of steroid effect. She had facial and neck swelling. Id.

On December 5, 2013, petitioner went to Presence St. Joseph Medical Center Emergency Room ("ER"), complaining of facial swelling, possible allergic reaction, sore throat, myalgias, right ankle arthralgia, diarrhea, and oral thrush. Med. recs. Ex, 3, at 5.

On December 7, 2013, petitioner returned to the same ER, complaining of bilateral leg pain. Id. at 23. She saw Dr. Ryan M. Pizinger, and complained that she had bilateral lower extremity pain and numbness. Id. at 27. Dr. Pizinger notes that petitioner had reactions to multiple things over the prior few weeks. She initially received flu vaccine and was put on antibiotics, which did not work. Then she was put on a different antibiotic and developed an allergic reaction. Over the last 24 hours, she had increasing pain in her lower extremities and numbness. On physical examination, she had full range of motion, normal strength, and normal sensation except for numbness and tingling in the tips of her toes and in all her fingertips. Her strength was 5/5 distally in her lower extremities. An x-ray of petitioner's lumbar spine showed moderate disk degeneration. The pain in her lower extremities had resolved. She had no symptoms. Her neurologic examination was normal except for numbness in the tips of her fingers and toes. Id.

The discharge summary issued on December 8, 2013. Id. at 30. Petitioner was diagnosed with resolved bilateral leg pain. She had a history of HIV. She did not have a urinary tract infection. She had anemia. Her CD4 count was above 900. She was known to have back pain. She had a questionable allergic reaction to Avelox and had been on prednisone. Id.

Also, on December 8, 2013, Dr. Daniel Magdziarz of Provena St. Joseph Medical Center ER wrote that petitioner had complained of bilateral leg pain. Med. recs. Ex. 8, at 13. She had a "flight of ideas." Id. She reported abdominal pain for three weeks on December 7, 2013, but on December 8, 2013, she denied abdominal pain. She reported some sore throat and urinary retention over the weeks. Id. She denied any tingling or numbness and then admitted to some tingling and numbness in both legs. Id. at 14. She reported she had this since last evening and in the past associated with back pain, although her time frame was vague. Id. On physical examination, her strength was 5/5 proximally and distally in her arms and legs. Her deep tendon reflexes were 2/4 in her legs. Her sensation was intact to touch in both arms and legs. Her motor ability was intact and symmetrical in both arms and legs. His differential diagnosis was back pain, radiculopathy, encephalopathy, and dementia. Her neurologic examination remained non-focal. Id.

On December 12, 2013, petitioner saw Dr. Miguel G. Camara, an allergist. Id. at 9. He noted that petitioner was highly allergic to penicillin, sulfa, Levaquin, silver, Avelox, and Flagyl. She had no complaints concerning her musculature and no neurological complaints. Id. She was overweight at 178.2 pounds. She had moderate face swelling. Id. Dr. Camara diagnosed petitioner with an adverse reaction to Avelox consisting of angioedema. Id. at 10.

On December 19, 2013, petitioner saw Dr. Rajeev H. Mehta, an ENT specialist, complaining of hoarseness which had been gradual and occurring in a persistent pattern for two months (which would put onset before the November 4, 2013 flu vaccination). Med. recs. Ex. 4, at 4. She was breathy and raspy. She had neck swelling and occasional sore throat. Her personal care physician prescribed Cefdinir, Avelox, and prednisone, none of which relieved her symptoms. Petitioner said she could feel sores in her throat when swallowing and complained of a poor sense of smell and taste for two to three months (also putting onset before the November 4, 2013 flu vaccination). Id.

On January 4, 2014, petitioner went back to St. Joseph, complaining of swelling of her face, neck, and back for the past month. Med. recs. Ex. 3, at 108. She saw Dr. Garganera, an infectious disease specialist, who opined that she seemed to have "accelerated HIV related lipodystrophy," which her HIV medications could cause, plus she had been on multiple other medications related to her HIV that could cause this condition. Id. at 109.

Also on January 4, 2014, petitioner saw Dr. Mary E. Monaco, a neurologist. Med. recs. Ex. 3, at 266. On Friday, November 29, 2013, petitioner said she was able to walk without difficulty and shop at multiple stores. But the Sunday after Thanksgiving, she started to have a raspy voice, swelling of her face and extremities. The leg swelling lasted about 14 hours and then resolved. She saw her personal care physician and an ENT and started on antibiotics and a steroid pack. She started to have atrophy of her legs and had numbness of her arms and legs. She had weakness and had difficulty rising from a seated position. She had a gait abnormality and had been using a walker. She stated she had cramps in her lower extremities, low back pain, and a history of right and left peroneal and sural neuropathy. On physical examination, she had weakness of the proximal muscles of her upper extremities. Id. She had weakness of the lower extremities, proximal greater than distal. Med. recs. Ex. 10, at 3. She had atrophy of her lower extremities, right greater than left. She had diminished vibratory sensation of both lower extremities, diminished pinprick of both upper and lower extremities, and reduced reflexes in her upper extremities and knees, with absent ankle reflexes. Id.

On January 6, 2014, an MRI of petitioner's thoracic spine showed mild to moderate degenerative changes. Id. at 223.

Also, on January 6, 2014, Dr. Monaco did an EMG and nerve conduction study on petitioner. Id. at 215. It was abnormal. Petitioner had right and left median motor and sensory neuropathy, right and left peroneal neuropathy, worse on the right than the left tibial neuropathy, right and left sural neuropathy, and denervation potentials in the left abductor pollicis brevis muscle secondary to the median neuropathy. Id. She had a history of bilateral peroneal and sural neuropathy. Id. at 218.

On January 8, 2014, Dr. Nitin V. Nadkami, a neurologist, noted petitioner had a subacute onset of neuromyopathy. Med. recs. Ex. 12, at 19. On the same date, Dr. Tamir Y. Hersonskey

noted petitioner had a longstanding neuropathy of the lower extremities. Id. at 24.

On January 9, 2014, in an addendum diagnosis by Dr. Carrie Y. Inwards of the Mayo Clinic, she stated these findings were nonspecific. Med. recs. Ex. 3, at 132.

On January 11, 2014, Dr. Subhash K. Patel performed an EMG on petitioner. Med. recs. Ex. 12, at 32. Petitioner had bilateral median neuropathy, bilateral peroneal neuropathy, right greater than the left tibial neuropathy, and bilateral sural neuropathy. The protein in her cerebrospinal fluid was 43, which was normal. Her cortisol level was low at 0.3. Id. Dr. Patel diagnosed petitioner with progressive weakness with atrophy. His suspicion was that she had myopathy. A muscle biopsy was done and he awaited the results. Id. at 33.

On January 13, 2014, Dr. Harry G. Brown reported that the muscle biopsy of the right quadriceps was negative for inflammatory infiltrates. Med. recs. Ex. 3, at 112. The type 2 fiber atrophy was significant. The findings suggested a neuropathic cause although drug effect and disuse were also possibilities. Id. The tissue findings were mild regenerative-degenerative changes denoting mostly type 2 fiber atrophy with many angulate atrophic fibers. Id. at 113.

On February 26, 2014, petitioner sought a second opinion from Dr. Thomas J. Kelly, a neurologist at the University of Chicago Medical Center. Med. recs. Ex. 7, at 286. She wanted to know the cause of her weakness. She had severe atrophy in her right quadriceps with lesser atrophy in both calves and left quadriceps. Id. at 289. Dr. Kelly was unsure of the cause of these symptoms, but stated, "There is no evidence for Guillain-Barré syndrome or myositis." Id. at 290. Dr. Kelly thought petitioner might have a preexisting neuropathy secondary to her HIV medication regimen or chemotherapy of colon cancer with a superimposed myopathy, but the origin of this myopathy was unclear. Id.

On March 20, 2014, petitioner had an EMG done at the University of Chicago Medical Center. Id. at 295. Petitioner's strength in her right quadriceps was 3+/5 and in her left quadriceps it was 4+/5. Some of petitioner's weakness appeared to be effort-related. Id. She had 5-/5 weakness in right foot eversion which also had an effort-related component. Id. at 296. Petitioner's deep tendon reflexes were 1+ at the knee and absent at the ankles. The EMG was abnormal. She had length-dependent axonal polyneuropathy. There was no evidence of a myopathy, demyelinating neuropathy, or lumbar radiculopathy. Id.

On April 2, 2014, petitioner saw Dr. Shwetha Manjunath. Med. recs. Ex. 9, at 7. The results of petitioner's ACTH stimulation test were abnormal. Id. at 8. She had adrenal insufficiency whose cause was unclear. The cause could be HIV. Adrenal insufficiency is an established endocrine problem in patients with HIV. Id.

On April 4, 2014, petitioner saw Dr. Jose T. Bolanos, an infectious disease expert. Med. recs. Ex. 13, at 22. Petitioner had right ankle pain for which she was seeing her podiatrist Dr. George. She continued physical therapy for her right leg due to weakness. She had ongoing easy bruisability. She reported a lot of stress due to family issues. Dr. Bolanos's assessment was

neuropathy with unclear etiology, possibly due to HIV infection, antiretroviral therapy, diabetes mellitus, and spinal stenosis. EMG/NCV studies done January 6, 2014 showed bilateral median neuropathy, and peroneal, tibial, and sural neuropathy without evidence of radiculopathy. She also had bruising of unclear etiology. Id.

On March 3, 2015, Dr. Vincent Benig, petitioner's personal care physician, filled out a VAERS report stating petitioner had face edema, right leg atrophy, and weakness starting November 22, 2013 after flu vaccine. Med. recs. Ex. 2, at 5. This was 16 months after she received flu vaccine on November 4, 2013.

On May 26, 2015, petitioner saw Dr. Benig complaining of back pain and suprapubic pain radiating to her low back one hour after eating, lasting several hours. Med. recs. Ex. 7, at 15. Petitioner had a history of chronic diarrhea after her colon was resected in 1994 due to cancer. She normally had baseline diarrhea after every meal. She had daily calf cramps each morning for one minute which then went away completely. Her gait was normal. Id.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for flu vaccine, she would not have had the multiple complaints recorded in her medical records, but also that flu vaccine was a substantial factor in causing the multiple complaints recorded in her medical records. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). As for her allegation that flu vaccine caused her peripheral neuropathy, petitioner does not have demyelinating neuropathy but has had longstanding issues with various neuropathies, many of which predate her vaccination and which her doctors opined could be due to her HIV and its numerous medications. Her muscle atrophy

is also without cause.

The Vaccine Act, § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion. Although petitioner's personal care physician Dr. Vincent Benig filled out a VAERS form on March 3, 2015 to report petitioner had a reaction to flu vaccination, the medical records do not support that petitioner did have such a reaction. They support that she reacted to Avelox and that she has longstanding issues with muscle weakness and various neuropathies, none of which is demyelinating. The undersigned notes that Dr. Benig's VAERS report is also contrary to his earlier medical records noting petitioner's swollen face was due to steroid injections or, according to Dr. Camara, fat redistribution from steroids in general.

In addition, petitioner has not filed a medical expert report in support of her allegations and her counsel admits that she cannot find an expert to support petitioner's allegations.

The undersigned **GRANTS** petitioner's oral motion to dismiss and **DISMISSES** this case for failure to prove a prima facie case of causation in fact.

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[4]

IT IS SO ORDERED.

Dated: May 5, 2017

/s/ Laura D. Millman
Laura D. Millman
Special Master

[4] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.